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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/600,173	BECK ET AL.
	Examiner	Art Unit
	Maureen M. Wallenhorst	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/20/03 & 5/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The disclosure is objected to because of the following informalities: On page 1 of the specification in the section entitled "Cross-Reference to Related Applications", the phrase –now US Patent no. 6,773,924, issued on August 10, 2004,-- should be inserted after the phrase "Application no. 10/371,783, filed February 21, 2003," so as to update the status of the parent application.

Appropriate correction is required.

2. Claims 3-5, 20-23 and 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 1 of claims 3-5, the phrase "the complex" lacks antecedent basis since claims 3-5 depend from claim 1, not claim 2 that positively recites a complex.

On lines 2-3 of claim 20, the phrase "wherein the parenterally acceptable liquid is a carrier or solvent" should be changed to –in a parenterally acceptable carrier or solvent—so as to make proper sense, similar to the wording of claim 19.

On line 1 of claims 21-23, the phrase "The solution" should be changed to –The composition—since claims 21-23 depend from claim 20 that recites an injectable composition.

On line 1 of claim 32, it is not clear what the abbreviation "AHS" stands for. The full meaning for this abbreviation should be included in claim 32. In addition, it is not clear if the recited percentages in claim 32 are percentages by weight or percentages by volume.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-5, 15-16 and 19-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-10, 12-13, 24-25, 27-31 and 40-41 of U.S. Patent No. 6,773,924 in view of Kararli et al (submitted in the Information Disclosure Statement filed on June 20, 2003).

Claims 8-10, 12-13, 24-25, 27-31 and 40-41 of US Patent no. 6,773,924 teach of a composition comprising an active hematinic species selected from the group consisting of ferric hydroxide sucrose complex, sodium ferric gluconate complex and ferric saccharate complex, wherein the composition is substantially free of excipients. These claims also teach of reconstituting the composition in a parenterally acceptable liquid such as water so as to inject the composition parenterally into a patient. Claims 8-10, 12-13, 24-25, 27-31 and 40-41 of US Patent no. 6,773,924 fail to teach of a parenterally acceptable buffering agent in the composition.

Kararli et al teach of a reconstitutable parenteral composition comprising in powder form, a therapeutic drug in an amount of about 30-90% by weight, a parenterally acceptable buffer in an amount of 5-60% by weight, and other parenterally acceptable excipient ingredients in a total amount not greater than about 10% by weight. The composition is reconstitutable in a parenterally acceptable solvent liquid to form an injectable solution. Kararli et al also teach of an article of manufacture comprising a sealed vial or container having therein a unit dosage amount of the composition in a sterile condition. The container is preferably a glass vial or ampoule. Optionally, the container can comprise two compartments, one to contain the reconstitutable powder and one to contain a solvent liquid in an amount sufficient to dissolve the powder. Kararli et al also teach of a method for treating or preventing a disease in a subject by reconstituting a unit dosage amount of the composition in a physiologically acceptable volume of a parenterally acceptable solvent liquid to form an injectable solution and injecting the solution parenterally into the subject. The parenteral administration of the composition encompasses injection or infusion such as intradermal, subcutaneous, intramuscular, intravenous, intramedullary, intra-articular, intraspinal etc. In one embodiment, the reconstitutable powder composition consists essentially of the therapeutic drug and the buffering agent. The buffering agent is selected to provide a pH of the composition upon reconstitution that is parenterally acceptable, is consistent with the therapeutic drug in the composition and provides a medium where the therapeutic drug is chemically stable. Suitable buffering agents include sodium and potassium phosphates, sodium and potassium citrates, mono, di- and triethanolamines, tromethamine and mixtures thereof. An especially preferred buffer is dibasic sodium phosphate. The pH of the composition is about 7 to 9, preferably about 7.5 to about 8.5. Excipients other

than the buffering agent, if present, constitute not more than about 10%, preferably not more than about 5% by weight of the composition prior to reconstitution. Water can be used to reconstitute the composition, but it is preferred to use an aqueous liquid containing a solute such as dextrose or sodium chloride.

Based upon the combination of claims 8-10, 12-13, 24-25, 27-31 and 40-41 of US Patent no. 6,773,924 and Kararli et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include a parenterally acceptable buffering agent in the parenteral composition taught by the claims of US Patent no. 6,773,924 since Kararli et al teach that a buffering agent in a parenteral composition is allows a pH to be established that is consistent with the therapeutic drug or agent present in the composition and provides a medium where the therapeutic drug or agent is chemically stable.

6. Claims 1-5, 24-27 and 30-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17, 19, 21, 25-26 and 42-43 of copending Application No. 10/858,163 in view of Kararli et al. For a teaching of Kararli et al, see previous paragraphs in this Office action.

Claims 17, 19, 21, 25-26 and 42-43 of copending application no. 10/858,163 teach of a composition comprising an active hematinic species selected from the group consisting of ferric hydroxide sucrose complex, sodium ferric gluconate complex and ferric saccharate complex, wherein the composition is substantially free of excipients. These claims also teach of an article of manufacture comprising a sealed container having a unit dosage amount of the composition therein. Claims 17, 19, 21, 25-26 and 42-43 of copending application no. 10/858,163 fail to teach of a parenterally acceptable buffering agent in the composition.

Based upon the combination of Claims 17, 19, 21, 25-26 and 42-43 of copending application no. 10/858,163 and Kararli et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include a parenterally acceptable buffering agent in the parenteral composition taught by the claims of application no. 10/858,163 since Kararli et al teach that a buffering agent in a parenteral composition allows a pH to be established that is consistent with the therapeutic drug or agent present in the composition and provides a medium where the therapeutic drug or agent is chemically stable.

This is a provisional obviousness-type double patenting rejection.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehmann et al (WO 99/07401, English language translation is US Patent no. 6,372,715, submitted in the IDS filed May 14, 2004) in view of Kararli et al. For a teaching of Kararli et al, see previous paragraphs in this Office action.

Lehmann et al teach of a composition suitable for parenteral administration into a patient, which comprises an iron complex as the active substance. The iron complex can be sodium iron (III) gluconate complex, which qualifies as a sodium ferric gluconate complex. Preferred iron preparations are Fe(II) complexes, especially those with a molecular weight of between 30,000 and 100,000 Daltons. Fe(III) saccharate is especially preferred. See lines 58-67 in column 3 and lines 1-10 in column 4 of US Patent no. 6,372,715. The iron preparation can be present in a solid form such as a lyophilized form. At the time of use, the lyophilizate can be reconstituted with a liquid such as a pharmaceutical usual injection media. See lines 42-51 in column 5 and lines 30-36 in column 6 of US patent no. 6,372,715. The composition containing the iron complex can be used alone as an individual composition in a powder form held within an individual unit container such as a glass ampoule. See lines 52-65 in column 5 and lines 27-36 in column 6 of US patent 6,372,715. The iron composition can also be used to treat iron metabolism disorders by reconstituting the lyophilized powder composition with a liquid and administering the composition parenterally to a subject. See lines 52-55 in column 7 of US patent 6,372,715. Lehmann et al. fail to teach of a parenterally acceptable buffering agent in the composition.

Based upon the combination of Lehmann et al and Kararli et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include a parenterally acceptable buffering agent in the parenteral iron composition taught by Lehmann et al since Kararli et al teach that a buffering agent in a parenteral composition allows a pH to be established that is consistent with the therapeutic drug or agent present in the composition and provides a medium where the therapeutic drug or agent is chemically stable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

October 18, 2004

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700